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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/058,480	01/24/2002	William John Martin		2239

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EXAMINER

FOLEY, SHANON A

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 11/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/058,480

**Applicant(s)**

MARTIN, WILLIAM JOHN

**Examiner**

Shanon Foley

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 1-3 and 10-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 4-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election without traverse of group III in the reply filed on July 23, 2004 is acknowledged.

Claims 1-3 and 10-14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected subject matter, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on July 23, 2004.

Claims 4-9 are under consideration.

### ***Information Disclosure Statement***

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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It is not clear what is intended by claim 9. Claim 9 states that the stealth virus infected cells are causing a non-malignant illness in a patient. If an illness is non-malignant, it is benign. If an illness is benign, how is it an illness?

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 4-9 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible asserted utility or a well established utility.

An asserted credible utility is assessed from the standpoint of whether a person of ordinary skill in the art would accept that the disclosed invention is currently available for such use.

In the instant case, the claims are drawn to a method of treating a stealth virus infection by exposing known or suspected virus infected cells within the patient to a magnetic field that only damages stealth virus infected cells in tissue culture. The claims also encompass stealth virus infected cells that are causing disease and/or cancer. These methods lack credible utility for several reasons.

There is no clear definition provided in the disclosure of what a stealth virus is. For example, on page 7, the disclosure states that a stealth virus infection was initially associated with psychiatric illness, chronic fatigue syndrome, and cancer. Further, on page 18, the disclosure states that stealth viruses have the capability of adopting and mutating genes from other viral, bacterial and cellular origins. However, there is no guidance provided for how a clinician would distinguish stealth virus infected patients from patients affected by psychiatric

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illness, chronic fatigue syndrome or cancer. In the example section starting on page 24 of the disclosure, it is stated that “[t]he culturing of stealth viruses is not yet a generally accepted method of research and/or clinical testing.” Therefore, it is not clear how stealth virus infected cultures were/are identified. It is also not clear whether the virus induces any detrimental effect on its own since patients identified as having stealth virus infection were already affected by other conditions or illnesses. Claim 5 requires that the stealth virus infected cells are causing diseases in animals. However, there is no correlation between a stealth virus infection and any disease. Since identification of distinguishing characteristics of a stealth virus infection is not provided, stealth virus infection cannot be determined.

The working examples describe the exposure of various cell clusters, which are presumably infected by stealth viruses, to magnets. There are also discussions regarding movement and/or change in shape of the cell clusters, changes in size and the appearance of pigmentation. However, there is no nexus between the observations made about these cell clusters and the disappearance of stealth virus titers or alleviation of any disease state or symptom. Further, since exposure of the magnet also results in “the loss of relatively normal appearing cells around clusters that had acquired more pigmentation...[this suggests] that certain cells had been unaffected by exposure to the magnet field.” The observation concluding this experiment is that, “the major effect on the culture from 12 hours exposure to a magnetic field, was the destruction and degeneration of many cells.” See the paragraph bridging pages 26-27. Therefore, since the method claimed is admitted to cause damage to abnormal and healthy cells in culture, there is no credible utility for exposing cells *in vivo* or *in vitro* to the claimed method. The prior art also indicates that exposure of virally infected cells to magnetic fields either

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exacerbates viral titer or has no effect on viral infection. Grimaldi et al. (Journal of Environmental Pathology, Toxicology and Oncology. 1997; 16 (2&3): 205-207) teach that exposure of Epstein-Barr virus infected cells to a magnetic field increased the number of cells expressing early antigens of the virus, see the entire reference. Further, Libertin et al. (Radiation Research. 1994; 140: 91-96) teach electromagnetic field exposure of the HIV-LTR to had no effect, see the abstract, the paragraph bridging pages 93-94 and Figure 5. Therefore, considering the lack of beneficial effects of magnetic field exposure on cells infected with other viruses, it is determined that the instantly claimed method has no credible utility.

On page 16, stealth viruses are defined as infectious agents that induce a characteristic vacuolating cytopathic effect (CPE) in culture cells. However, this phenomenon does not aid in clearly identifying characteristics of the virus to one of ordinary skill in the art. To illustrate this point, the teachings of Sahagun-Ruiz et al. (Virus Genes. 2004; 28 (1): 71-83) is cited. Sahagun-Ruiz et al. describe five open reading frames (ORFs) that were sequenced from a prototype stealth virus. Sahagun-Ruiz et al. describe this virus as a “heterogeneous group of atypically structured putative viruses that have been isolated from patients...” (emphasis added). Sahagun-Ruiz et al. further state that “[t]he biological significance of this entity is not yet clear, and it has not been independently replicated in tissue culture. “Stealth virus” sequences submitted to Genbank include sequences also reported in African Green Monkey Simian Cytomegalovirus, bacterial, fungal and human genomes.” See the first full paragraph of the second column on page 72 of Sahagun-Ruiz et al. From the discussion provided by Sahagun-Ruiz et al., it is clearly evident that stealth viruses have no distinguishing characteristics identifiable by those skilled in

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the art. In addition, since Sahagun-Ruiz et al. refer stealth viruses as "putative", it is apparent that there is doubt in the art as to whether stealth viruses even exist.

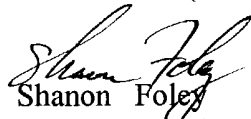
Claims 4-9 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon Foley whose telephone number is (571) 272-0898. The examiner can normally be reached on M-F 10:00 AM - 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Shanon Foley  
Primary Examiner  
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